

one end of each of said adjusting means is located on the respective one of said elastic tie-members, while the other end of each of said adjusting means is held to the respective one of said supports; and

such that a force arising between said supports and elastic tie-members is essentially one that compresses the spine and the limbs and does not prevent flexion, extension, rotation and motion of the limbs to a required position, as well as motions of the patient's trunk.

12. A device as set forth in claim 11,

wherein said means for adjusting the tension of the elastic tie-members are bands having one end connected to an elastic tie-member, and an other end held in a lock located on one of the supports.

13. A device as set forth in claim 11,

wherein said lock is a buckle with a square frame used in safety belts.--

REMARKS

The amendments to the claims are to cancel claims 7 to 10 without prejudice and to replace them as new claims 11 to 13.

New claims 11 to 13 have been written so as to recite sufficient structure and so as to be consistent to overcome the rejection under 35 U.S.C. 112. Withdrawal of this ground of rejection is respectfully requested.

As it is recited in lines 26-34 of page 5, and in lines 1-7 of page 6 of the present specification, the claimed device comprises supports placed on patient's trunk as follows. There is a pelvic support appearing as a belt, and there are shoulder supports. Also there are supports placed on patient's limbs as follows: elbow, hand, finger, knee and foot supports. All the supports mentioned above are interlinked through fixing elements appearing as elastic tie-members which may interconnect both adjacent and nonadjacent supports.

The elastic tie-members are arranged on the surface of the patient's body in substantially antagonistic pairs so as to follow the anatomical arrangement of the skeletal muscles. This means that each elastic tie-member has its antipode or opponent. That is to say that some of the elastic tie-members are located on the patient's body to the right of the spine, while the other tie-members are situated to the left of the spine. Also some of them are arranged at the front of the trunk and limbs, while the other ones are arranged at the rear thereof. That is, the words "opponent" and "antagonist" are the synonyms.

Thus, it is the disposition of the elastic tie-members in antagonistic pairs so as to follow the anatomical arrangement of

the skeletal muscles that is the construction arrangement of the device which is to accomplish the object of the invention. This desired result occurs if and only if the elastic tie-members are situated in a strict symmetry with respect to the spine and in accordance to the anatomical structure of human body.

According to the claimed construction, a clearly defined dynamic supporting structure is provided, appearing as a functional corset (lines 31-33 of page 6 of the specification). The use of this gives a possibility of restoring a new position to the patient's body and limbs closely resembling the physiological one.

Furthermore, the Examiner's allegation that "whether a device falls within the scope of the claims cannot be ascertained until a particular user engages the device" is contrary to fact.

The claimed device is aimed at treating patients with disturbed posture and motor activity. In particular, it is useful to treat infantile cerebral paralysis which exhibits such disturbances as triple flexion of the lower limbs complicated with contractures in the ankle joints, uncompensated forward incline of patient's body, difficult motion, pathological gate, and so on. That is why any patient needing treatment with the aid of the present invention can receive such treatment. This is because the invention enables the replacing of static (passive) correction of the pathological positions of the trunk and limbs with a functional (active) correction. The invention enables the rearranging of the previous pathologic stereotype of the posture and motions in the

central and peripheral nervous systems.

In view of the foregoing, it is believed that the scope of the claims for the claimed device is not indefinite irrespective of whether the device is tried by a particular user or not. Hence, the claims for patent are quite definite.

There were one or more inexact translations of the expression "pelvic supports" which follows the corresponding Russian noun in the plural form instead of the singular one. However, the drawings present only one pelvic support appearing as a belt and located at the waist (FIGS. 1-3).

Apart from the aforementioned construction features (i.e., elastic tie-members and supports) the device also comprises a plurality of means for adjusting the tension of the tie-members. Each of the tension means is interposed between the respective elastic tie-member and one of the supports, e.g., pelvic, knee, etc.

Provision of these means for adjusting the tension of the elastic tie-members makes it possible to vary and select the force of action produced by the tie-members on the musculoskeletal system of a patient. This is done individually depending on the form of the disease and degree of affection of the patient's locomotorium (lines 24-34 of page 4 of the specification).

Thus, each of the tie-members is tensioned through its tension adjustment means which connects the tie-member to one of the supports.

As stated in lines 2-9 of page 6 of the specification, said means for adjusting the tension of the elastic tie-members appear as bands having one of their ends connected to an elastic tie-member, while their other end is held to a lock which in turn is fastened on one of the supports.

The tension adjusting means of the elastic tie-members may have any other construction, such as being a lock provided they can perform a similar function.

In the following is an explanation of the expression "said supports". The word "said" implies any of the supports mentioned in the claims for patent, such as pelvic, shoulder, hand, finger, elbow, knee, and foot support.

An answer is provided for the Examiner's question as to "how can the joint position be 'fixed' without preventing movement of the joint?"

For the sake of clarity, it can be explained that the claimed device provides for fixing the patient's joints in a required position from the instant when a force arises contributing to flexion, extension, rotation, abduction, and adduction of patient's limbs and trunk as follows.

The device is put onto a patient with relaxed muscles and those elastic tie-members are tensioned which correct the position of the patient's body parts to be treated (e.g., deformed trunk and lower limbs).

The elastic tie-members are tensioned with the aid of tension adjusters until the normal physiological position is attained. That is, the elimination of a pathological arrangement of the trunk and limbs is attained but while retaining a possibility of performing motion with an amplitude approximating the maximum one in a given particular patient.

Thus, no contradiction is present in the specification of the present invention because the device described therein is to fix the parts of the patient's body in a required position relative to one another whenever the patient's muscles are relaxed. Thus, the myogenic tonus of a muscle or of a group of muscles is balanced by an elastic tie-member by increasing its tension until a load appears in a respective group of muscles which in turn makes it possible, in case of necessity, to perform some motions. This is because elastic retainers place no limitation on motion when parts of the patient's body perform spatial movements but only require additional efforts on the part of muscles. Every kind of patient's motions is ensured by elastic tie-members arranged on the surface of patient's body in antagonistic pairs so as to follow the anatomical arrangement of the skeletal muscles with respect to joints. This is the principal subject-matter of the claims.

In regard to the Examiner's question as to locks. As recited in lines 4-7 of page 6 of the specification, each tension adjuster of elastic tie-members comprises a lock (5) as shown in FIGS. 1 to 3.

The Applicants comment upon the prior art rejections of the claims as follows.

The Examiner's contention is respectfully traversed that U.S. Patent No. 5,186,701 to *Wilkinson* discloses the tension adjuster of elastic tie-members with a lock that has a construction similar to that recited in the claims.

However, the *Wilkinson* device comprises an adjuster of the length of an elastic cord with a lock rather than an adjuster of tension of elastic tie-members. This length adjuster differs in construction from the claimed means for adjusting elastic tie-members.

According to *Wilkinson*, the lock is located at one end of the elastic cord, while the tension adjuster is situated at the opposite end of the elastic cord running to the respective of the three pairs of supports.

The cord length adjuster performs the function of so adjusting the cord for length as to suit the anthropometric dimensions of human body. This differs greatly from the function performed by the tension adjuster of elastic tie-members in the claimed

invention.

The lock as taught by *Wilkinson* differs radically from the lock claimed in the present invention not only in construction but also in purpose.

The lock disclosed by *Wilkinson* shown in FIGS. 10 and 11 comprises the clamp of a lock for shoes, gloves, belt, etc., which has a hinge 118, a body 120 with a hole 124, a pin 122, a reed 126, a link 134 having a passage 138, a casing 136, and a hinge retainer 142.

The prior art lock functions as follows. The reed 126 engages the slot in the body 120, with the result that the pin 122 catches the hole 124, whereby the lock is closed.

In the present invention the lock is essentially a conventional buckle comprising a square frame used in buckles of safety belts.

As pointed out before, and as stated in lines 4-9 of page 6, the lock is a component of the tension adjuster of elastic tie-members, which may be of any construction performing a similar function. This is different from the lock disclosed by *Wilkinson*. This is because the prior art lock is intended for disconnecting the elastic elements from the support. The lock in the present invention is for fixing the degree of tension of an elastic tie-member required for a particular patient.

In the present invention, the operation of the means for adjusting the tension of elastic tie-members shaped as bands (4) and locks (5) is in such a manner that one end of the band (4) is connected to the respective elastic tie-member. The opposite end of the band (4) is connected to the supports (1) so as to fix the tension of the elastic tie-members (2).

Tensioning of the elastic tie-members shortens the elements shaped as the bands (4) and adapted for adjusting the tension of the elastic tie-members (2), with the result that a distance between the elastic tie-member (2) and the lock (5) is reduced.

It is under the effect of a tensile force applied to the end of the band (4) that the latter is released from the lock (5). The portion of the band (4) located on the opposite side of the lock (5) is contracted, thereby the elastic tie-members (2) get tensioned.

The bands (4) held to the lock (5) remain therein both before and after tensioning the elastic tie-members (2).

Furthermore, the prior art rejection of the claims under 35 U.S.C. 102(b) and 35 U.S.C. 103(a), as being anticipated by or obvious over U.S. Patent No. 807,908 issued to Bradstreet, is traversed.

Bradstreet teaches only two supporting elements located on the feet (D) and the waist and appearing as strap 1, and a belt pelvic

support (3). The term "support" implies necessarily the presence of a zone of application of the forces exerted by elastic elements.

The oblique and ring-shaped grids located round the ankles, under the knees, on the shoulder girdle, in the region of the elbow, and at the wrist (Ref. Nos. 7, 13, 12, 22, respectively) are not in fact the supporting elements. This is because they cannot perform the function of such elements as being readily displaceable under the action of the forces exerted by the main longitudinal elastic straps. They do not serve as displacement restrictors of these longitudinal straps. The device comprises two main elastic straps which establish a single system of tie-members and run lengthwise between the trunk and the thighs from the anchoring points on the belt at the front. Then they are thrown over the shoulders, and run down to the anchoring points on the belt at the rear and then run further from these points to the lower limbs. Thus they prolong the system downwards. The front and rear straps are bifurcated at the thigh and go the lateral surfaces of the shin and to the feet to be held there in position. Provision is also made for a plurality of transverse and obliquely running small straps on the trunk and arms.

Thus, the elastic straps taught in Bradstreet (that is, the respective front and rear straps 4, 5; the obliquely running straps 8; the thoracic straps 11; the arm straps 14; the main straps 20, 21 running along the thigh; the thigh strap 27; and the shin strap 23) are not arranged in antagonistic pairs. Nor are they connected to two supports as assumed by the Examiner. The aforesaid support

3 appearing as a belt and serving as the pelvic support, performs but a limited function consisting mainly in pressing the vertical straps against the trunk.

Thus the *Bradstreet* device is constructed as a single system not interconnected by any supports and is essentially an enclosed space featuring the force application points at the shoulders and feet. Moreover, the *Bradstreet* system does not comprise a means (A) for adjusting the straps for tension. FIG. 6 presents a means for interconnecting the vertical elastic straps with the aid of which these straps can be positioned at any place wherever it becomes necessary, e.g., at the wrists, ankles, etc.

Because *Bradstreet* is devoid of independently functioning elastic tie-members exerting action upon the individual groups of muscles, *Bradstreet* does not teach correcting the mutual position of the parts of the patient's body. Thus, *Bradstreet* will not find application for treating neurological disorders, in particular, infantile cerebral paralysis.

The principal distinguishing feature of the claimed elastic tie-members of the invention resides in their being shaped as bundles 18 to 26 in number and being used in a plurality of variants and with variable anchoring points with respect to both bottom and top ends of tie-members.

Elastic tie-members are largely interposed between the neighboring support elements separately for the trunk and limbs, in

such a manner: shoulder supports and pelvic support in the form of a belt - on the trunk; hand support in the form of a glove, elbow support, shoulder support - on the arms; pelvic support, knee support, shoe; and knee supports, shoe - on the legs.

The claimed device comprises also obliquely running elastic tie-members, each having its own tension adjuster.

Additionally, the claimed device is devoid of any connection between the leg and the hand or between both hands and hence of any influence of one hand on the other or on the leg. This allows for independent correction of the foot, shin, and thigh for repositioning thereof.

As regards, the supports claimed in the present invention, each and every one of them are the zones of application of forces exerted by the elastic tie-members. That is, all the supports feature elastic tie-members terminating therein and other ones starting therefrom. They are arranged in antagonism pairs (the concept of antagonism being applied to the joints) with due account for the anatomical arrangement of the skeletal muscles.

Thus, for instance, the shoulder supports are fashioned as wide straps, wherein their lower portion comprise anchoring elements of the elastic tie-members. These supports are located from the neck to the shoulder joint. They are intended for developing an adequately high friction between the strap and the patient's body with due account for keeping the strap against

slipping. This is in case of an asymmetric loading with the elastic tie-members at the front and rear.

It is due to the shoulder supports that different tension forces are applied at the breast and back, thus causing the trunk to flex or extend. The elbow supports of the present invention are shaped as circular cuffs encompassing the region of the elbow joint. Provision of elbow supports is aimed at connecting the elastic tie-members that run on one side from the shoulder and on the other side from the hand. This makes possible the functional loading of separate forearm and shoulder muscles during a treatment process.

The claimed device of the present invention comprises knee supports. Each is fashioned as a plate which encompasses the anterior and the lateral knee surfaces and has fastening straps on the rear surface. There are fastening elements in the form of a plurality of elastic tie-members running from above along the thigh and from below along the shin.

The knee supports are used in the present invention for connecting the elastic tie-members. In addition, they subdivide the tie-members into two tiers, for the shin and for the thigh. It is due to connection of the elastic tie-members to the knee supports that correction of the foot, shin, and thigh for proper positioning can be performed independently in the claimed device. This extends the possibility of using diverse therapeutic techniques and modalities.

The pelvic support appearing as a wide exertion belt is also the zone of application of the forces developed by the elastic tie-members.

In the claimed invention, the trunk elastic tie-members that run from above, terminate in the pelvic support. Then starting at the pelvic support are the leg elastic tie-members running downwards therefrom. The pelvic support develops loads on the upper or lower trunk portion.

All of the above differences prove the unique construction of the present invention which differs substantially from the one taught by *Bradstreet*.

The Stevens U.S. Patent No. 3,295,517, discloses a device which comprises only two main elastic straps running along the extero-lateral surfaces of the legs and anchored from above to the waistcoat and from below to the feet through a loop. The transverse straps on the thighs and shins serve only for keeping the main longitudinal straps in a required position. Such a construction fails to provide a possibility of correcting the body parts for mutual position by having at one's disposition only two elastic straps with a limited zone of action.

The principal distinguishing feature of the claimed device resides in the provision of a plurality of elastic tie-members interposed in pairs between the supporting elements on the anterior, posterior, and lateral surfaces of patient's body. There

is also the presence of force-exerting supporting elements, that is, the belt-shaped pelvic element, as well as on the knees, feet, elbows, wrists, and fingers.

Also, the Examiner points to the buckle taught by *Stevens*.

However, the *Stevens* device shows articulately joined snap-action fasteners (FIGS. 4, 6). These are part of the means for adjusting the tension of the main straps located at the ends of the first and second transverse straps. They serve for detachable holding of the ends of each transverse strap to each other with a possibility of adjusting both of them to establish a pressure applied radially and inwardly to the user's thighs and legs.

The elastic straps are passed directly through each of the snap fasteners so that the tension of said straps is fixed by the fasteners.

FIG. 3 illustrates that used as the tension adjustment means are flat elastic straps as distinct from the ones set forth in the present invention which are made from round-section ties and have other characteristics of elastic forces. That is why the elastic tie-members of the claimed device, as distinct from the device as taught by *Stevens*, are connected to the retaining lock through an adjusting band rather than directly. This fact is mentioned before in describing the construction of the means for adjusting the tension of the elastic tie-members.

In view of the foregoing, the prior art means cannot be used for establishing a normal physiological stereotype of posture and motions in patients with disturbed posture and motor activity. This is because the known snap fastener is aimed at performing other functions.

The Patent Examiner has stated that the Rule 132 Declarations and Exhibits do not overcome the prior art rejections of the claims.

The submitted documentary materials prove both the novelty and importance of the invention which relates only to the claimed device and confirm its unobviousness. The name "Adeli" is a trade mark for the therapeutic loading device claimed herein. All the documents that have been submitted represent an analysis of the operation with the use of the claimed device. Presented are conclusions on its clinical trials for treatment of patients with disorders of the locomotorium. The expression "Method" is used in the text by physicians with a view to represent the fact that the claimed device opens a possibility of its introduction into medical practice for treating patients suffering from such a severe affliction as infantile cerebral paralysis. Naturally, the medical practitioners called the use of the claimed device as the means for practicing a new "Treatment method". In this regard, the claimed device named "Adeli" by its inventor is recommended now according to the results of its clinical trials for use in medical practice. It is believed that this will be a clarifying explanation.

It is known that the following criteria of evaluation of the nonobviousness of the claimed device are to be considered according to the provisions of Rule 132, as related to objective characteristics.

The Rule 132 Exhibits A to F show commercial success accompanying the use of the present invention; show overcoming difficulties encountered during solution of the problems solved by the present invention; show technical progress; show solution of a problem that could not be solved for a prolonged period of time; show new and unexpected results attained; show acquiring corresponding patents for the present invention abroad, where over twenty patents have been granted abroad; and show high expenses concerned with research and development work.

The evidence of new and unexpected results and of commercial success that have been submitted earlier is commensurate in scope with the patent claims for the device and meet fully the aforementioned criteria of nonobviousness and conditions to show patentability.

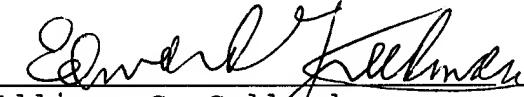
Enclosed is an Information Disclosure Statement with copies of PTO-Form 1449 and PTO-Form 892.

In conclusion, the Applicants believe that the device for treatment of patients with disturbed posture and motor activity, is patentably distinct under 35 U.S.C. 103 over all the prior art references applied by the Patent Examiner. Claims 7 to 10 have

been canceled without prejudice. New claims 11, 12, and 13 have been added. Applicants believe that this application is now in condition for allowance. Early allowance of the claims and the application based upon the merits of these claims is respectfully requested.

Respectfully submitted,

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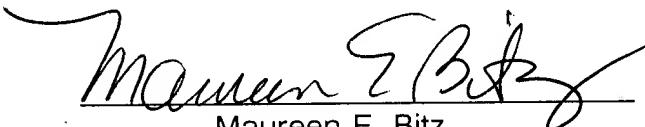
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- Enclosure:
1. Copy of Petition for three month extension of time
 2. Information Disclosure Statement with copies of PTO-Form 1449 and PTO-Form 892

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: ASSISTANT COMMISSIONER FOR PATENTS, Washington, D.C. 20231, on May 20, 1997.

Date: May 20, 1997


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